

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Barbara S. SLUSHER *et al.*

Art Unit: 1618

Appln. No.: 09/866,961

Examiner: Zohreh FAY

Filed: May 30, 2001

Atty. Docket: 20595.160

For: *NAALADase Inhibitors for Treating
Retinal Disorders and Glaucoma*

Confirmation No.: 7379

Application for Patent Term Adjustment

Mail Stop - Petitions

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicants respectfully request reconsideration of the Patent Term Adjustment ("PTA") as specified in the Determination of Patent Term Extension under 35 U.S.C. §154(b) ("Notice"), mailed on December 29, 2006. Applicants herein apply for an extension of the patent term beyond that calculated by the U.S. Patent and Trademark Office ("Office"). The Notice specified a PTA of 622 days (according to Private PAIR the 622 days is calculated using 703 days due to USPTO delay minus 81 days due to Applicants' delay). Applicants respectfully request that the Office reinstate the 81 days of patent term reduced pursuant to 37 C.F.R. § 1.704(b) and accord Applicants a PTA of 1136 days pursuant to 37 C.F.R. § 1.702(b).

In support of this application, Applicants set forth the following Statement of Facts.

Statement of Facts

1. On May 30, 2001, the instant application was filed.
2. On October 23, 2002, the Office mailed a Restriction Requirement. According to 37 C.F.R. §1.703(a)(1), the patent term is adjusted by **85 days** due to Office delay.*
3. On November 12, 2002, Applicants filed a Response to the Restriction Requirement.
4. On February 14, 2003, the Office mailed a first non-final Action on the merits.
5. On May 12, 2003, Applicants filed a response to the Office Action of February 14, 2003.
6. On September 16, 2003, the Office mailed a second non-final Action on the merits. According to 37 C.F.R. §1.703(a)(2), the patent term is adjusted by **4 days** due to Office delay.*
7. On December 16, 2003, Applicants filed a response to the Office Action of September 16, 2003.
8. On January 29, 2004, the Office mailed a final Action. The Action was noted as being responsive to amendments and remarks filed by Applicants on October 17, 2003. Without addressing Applicants' response filed on December 16, 2003, the Action reiterated the arguments previously presented in the non-final Action of September 16, 2003.
9. On April 8, 2004, Applicants responded to the final Action by sending a courtesy copy of the December 16, 2003, response (along with a request to rescind the non-final Office Action).
10. On July 7, 2004, the Office mailed an advisory action, stating that Applicants' response of April 8, 2004, failed to place the Application in condition for allowance.
11. On July 19, 2004, at SPE Christopher Low's suggestion, Applicants filed a request for withdrawal of the July 7, 2004, Advisory Action and the January 29, 2004, Office Action. According to Private PAIR, the Office is considering this petition to be Applicants' Amendment after Final Rejection and is incorrectly reducing the patent term adjustment by **81 days** under 37 C.F.R. § 1.704(b). In fact, Applicants' April 8, 2004, filing (cited

* The time period for this PTA overlaps, however, with the time period for the PTA under 37 C.F.R. §1.703(b) (1136 days) and thus, according to 37 C.F.R. §1.703(f), Applicants are only entitled to the PTA of 1136 days.

above) was Applicants' response to the final Office Action and was filed within three months of the mailing date of the Office Action mailed January 29, 2004.

12. On July 26, 2006, the Office mailed a "responsive Action" (non-final Action). According to 37 C.F.R. §1.703(a)(2), the patent term should be adjusted by at least **831 days** due to Office delay in responding to Applicants' July 19, 2004, request for withdrawal of the July 7, 2004, Advisory Action and the January 29, 2004, Office Action.* According to Private PAIR, the Office calculated 614 days because it counted the days from Applicants' July 19, 2004, filing (which was a Request for Withdrawal of Office Actions) instead of Applicants' December 16, 2003, filing.
13. The patent is scheduled to issue on July 10, 2007. According to 37 C.F.R. §1.703(b), the patent term should be adjusted **1136 days** due to Office delay.
14. The patent issuing from this application is not subject to a terminal disclaimer.
15. There were no circumstances constituting failure on the part of Applicants to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. §1.704.

* The time period for this PTA overlaps, however, with the time period for the PTA under 37 C.F.R. §1.703(b) (1136 days) and thus, according to 37 C.F.R. §1.703(f), Applicants are only entitled to the PTA of 1136 days.

Remarks

According to 37 C.F.R. §1.702(b), the term of an original patent shall be adjusted if the Office fails to issue a patent within three years of the actual filing date of the application. The current application was filed on May 30, 2001, and the patent should issue on July 10, 2007.¹ The Office did not provide Applicants with any PTA for this delay. Applicants are entitled to a PTA of 1136 days due to failure of the Office to issue the patent within three years of the actual filing date of the application. *See* 37 C.F.R. §1.703(b). Private PAIR does not account for any addition time for this delay.

According to 37 C.F.R. §1.702(a)(1), the term of an original patent shall be adjusted if the Office fails to mail a notice under 35 U.S.C. 132 within fourteen months after the date on which the application was filed under 35 U.S.C. §111(a). The Office correctly calculated the examination delay in this application (85 days), due to failure of the Office to respond within fourteen months to Applicants' filing under 35 U.S.C. §111(a). *See* 37 C.F.R. §1.703(a)(1). Private PAIR correctly states that the PTA for this portion of prosecution is 85 days. According to 37 C.F.R. §1.703(f), however, the term of a patent entitled to adjustment under 37 C.F.R. §§ 1.702 and 1.703 shall be adjusted for the sum of the periods calculated to the extent that such periods are not overlapping. Since the period under 37 C.F.R. §1.702(b) (1136 days) overlaps with the period under 1.702(a)(1) (85 days), Applicants are entitled to the 1136 days but not the 85 days under 37 C.F.R. §1.702(a)(1).

According to 37 C.F.R. §1.702(a)(2), the term of an original patent shall be adjusted if the Office fails to respond to a reply under 35 U.S.C. 132 within four month after the date on which the reply was filed. The Office correctly calculated the examination delay in this application (4 days), due to failure of the Office to respond within four months to Applicants' May 12, 2003, reply under 35 U.S.C. 132. *See* 37 C.F.R. §1.702(a)(2). Private PAIR correctly states that the PTA for this portion of prosecution is 4 days. According to 37 C.F.R. §1.703(f),

¹ Provided that the issue fee is paid on the date that is three months after the mailing date of the Notice and the patent issues on the Tuesday before the date that is 28 weeks after the mailing of the Notice.

however, the term of a patent entitled to adjustment under 37 C.F.R. §§ 1.702 and 1.703 shall be adjusted for the sum of the periods calculated to the extent that such periods are not overlapping. Since the period under 37 C.F.R. §1.702(b) (1136 days) overlaps with the period under 1.702(a)(2) (4 days), Applicants are entitled to the 1136 days but not the 4 days under 37 C.F.R. §1.702(a)(2).

Also according to 37 C.F.R. §1.702(a)(2), the Office calculated a PTA of 614 for failure of the office to respond to Applicants' July 19, 2004, amendment after final rejection. This calculation is incorrect as the Office should have calculated the days from Applicants' December 16, 2003, filing. This would result in a PTA of 831 days. *See* 37 C.F.R. §1.703(a)(3). According to 37 C.F.R. §1.703(f), however, the term of a patent entitled to adjustment under 37 C.F.R. §§ 1.702 and 1.703 shall be adjusted for the sum of the periods calculated to the extent that such periods are not overlapping. Since the period under 37 C.F.R. § 1.702(a)(2) (831 days) overlaps with the period under 37 C.F.R. § 1.702(b) (1136 days), Applicants are entitled to the 1136 days but not the 831 days under 37 C.F.R. §1.702(a)(2).

According to 37 C.F.R. §1.704(b), there will be a reduction of the PTA period for any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request. The reduction would be the number of days beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. Private PAIR shows a reduction to the PTA of 81 days. This reduction is presumably because the Office erroneously considered Applicants' July 19, 2004, request for withdrawal of the Office Action to be the response to the final Office Action mailed January 29, 2004. However, the Office withdrew the final Office Action in its Petition Decision of January 19, 2005, and issued in its place a non-final Office Action on July 28, 2006.

In summary, Applicants assert that they are entitled to a PTA of **1136** days under 37 C.F.R. §1.702(b).

Applicants respectfully request that the Office remove the 81 day PTA reduction in accordance with 37 C.F.R. §1.704(b) and accord the present application with a PTA of **1136** days.

Authorization to charge the \$200.00 fee under 37 CFR 1.18(e), and any additional fees due in conjunction with this filing, is given in the accompanying transmittal letter.

Respectfully submitted,

A handwritten signature in black ink that reads "Danielle Edwards". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Suet M. Chong (Reg. No. 38,104)
Danielle M. Edwards (Reg. No. 51,645)

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